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Subject	U.S. Patent Application Serial No.: 10/027,343; Entitled: RECONFIGURABLE SURGICAL APPARATUS; inventor: Tony Looper
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Following this coversheet – Reply Brief on Appeal Under 37 C.F.R. § 41.71

Attorney Docket Number: VM6117/ALL8057

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS

In re Application of:

Inventor:	:	Looper, Tony	) Examiner: Vrettakos, Peter J.
Serial No.	:	10/027,343	) Art Unit: 3739
Filing Date	:	Dec., 19, 2001	)
Title:	:	Reconfigurable Surgical Apparatus	)
Attorney Docket	:	VM6117/ALL8057	)

CERTIFICATE OF FACSIMILE TRANSMISSION

Date of Deposit: July 14, 2005

I hereby certify that this correspondence is being sent via Facsimile to the attention of Examiner Vrettakos at Facsimile Number: 571-273-4775; c/o The United States Patent and Trademark Office, Appeal Brief-Patents, Alexandria, VA 22313-1450.

Christine Cameron
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REPLY BRIEF ON APPEAL UNDER 37 C.F.R. § 41.71

Hon. Commissioner of Patents and Trademarks
P. O. Box 1450
Alexandria, VA 22313-1450
Dear Commissioner:

This is the reply appeal brief under 37 C.F.R. 41.71 for the appeal filed January 7, 2005 in the above captioned case, appealing the Office Action of November 2, 2004 in which the Examiner finally rejected all pending Claims 43-84.

Respectfully submitted,

Donald O. Nickey July 14, 2005

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REPLY BRIEF ON APPEAL

I. BRIEF PROCEDURAL HISTORY

This reply brief is filed under 37 C.F.R. §41.41 in response to the Examiner's Answer, mailed on June 9, 2005.

II. SUMMARY OF THE ARGUMENT

In the Examiner's Answer, mailed on June 9, 2005, the Examiner continues and expands upon three primary errors in his analysis of the instant application relative to the cited prior art of Freitas (U.S. Pat. No. U.S. Pat. No. 5,486,185). These errors include:

1. The Examiner incorrectly analogizes the moving probe sleeve which moves translationally to actuate the surgical tool of Freitas, with the non-moving hollow manipulation shaft of the instant invention, which passively contains the moving prime mover of the apparatus.

2. The Examiner mistakenly interprets the term "rotably engage" as the ability to transfer rotable force in the Freitas device; as the Freitas probe, because of the nature of its engagement with its surgical tool, cannot transfer rotational force. On the other hand, the entirely different nature of the coupling between the prime mover and the surgical tool of the instant invention makes it inevitable that any rotational force on the prime mover will be immediately and positively transmitted to the tool.

3. Unlike the instant invention, Freitas has no "frangible portion."

III. REPLY ARGUMENT IN DETAIL

1. The Moving Probe Sleeve (28, 68, 112) Which Moves Translationally To Actuate The Surgical Tool (20) Of Freitas, Is Not Analogous With The Non-Moving Hollow Manipulation Shaft (120) Of The Instant Invention, Which Passively Contains The Moving Prime Mover (130) Of The Apparatus.

Details of the probe sleeve (28, 68, 112) and probe (52, 104) of Freitas are shown in the following drawings taken from the Freitas patent (U.S. Pat. No. 5,486,185).

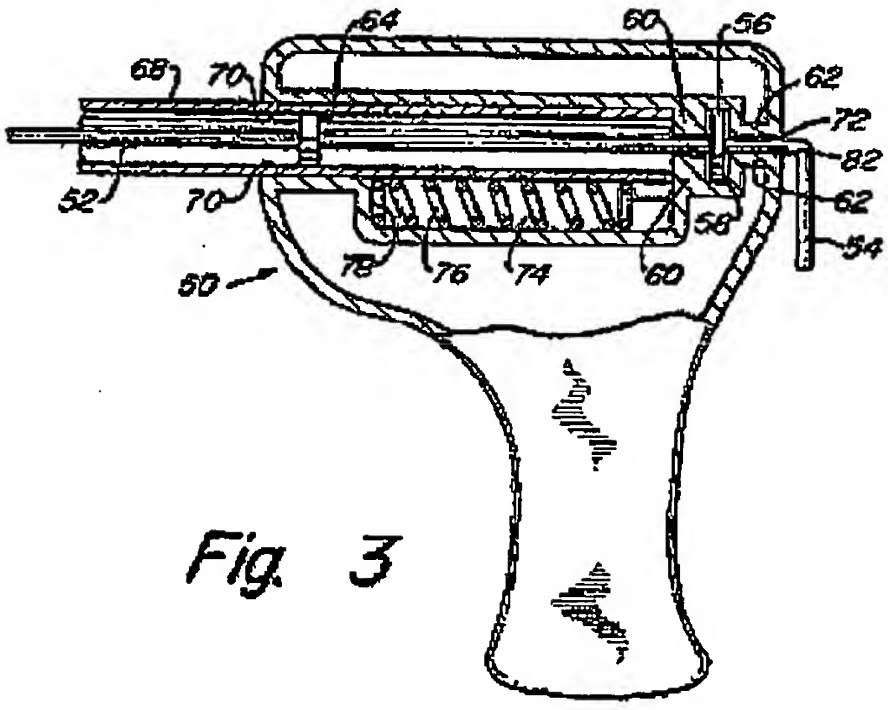


Fig. 3

(Fig. 3 of Freitas)

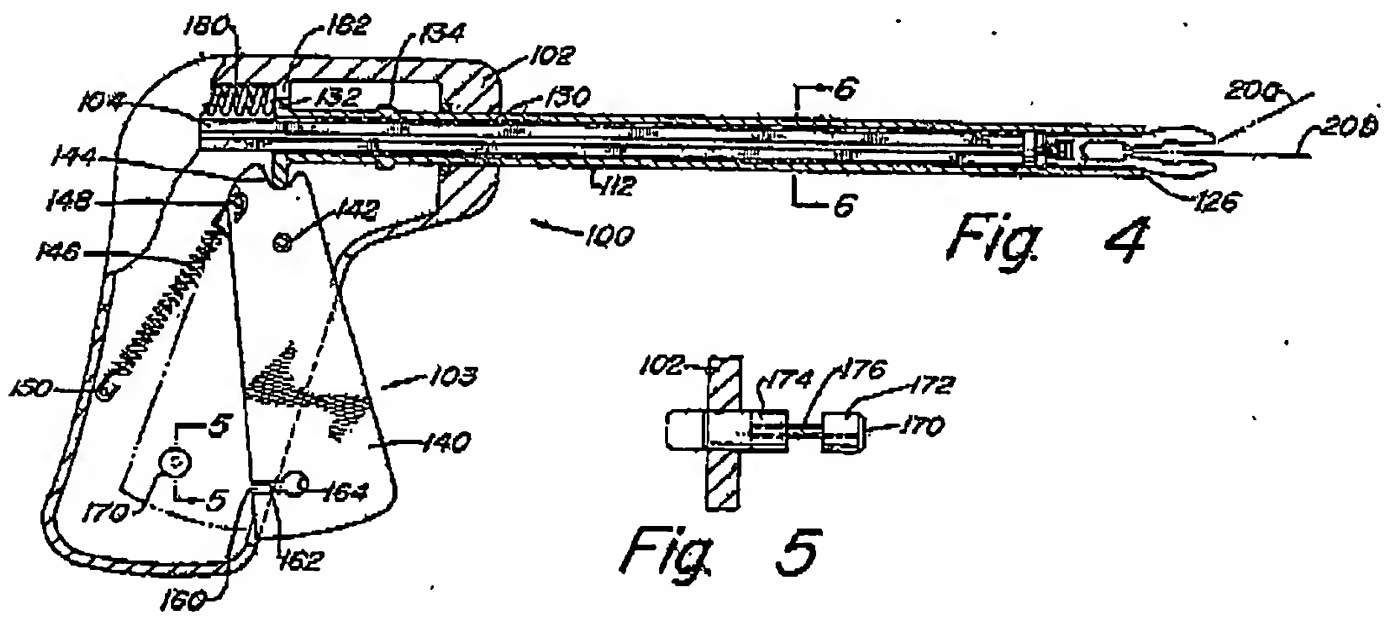
Fig. 3 illustrates a partial transverse section through the main body of the Freitas device. Freitas' probe (here labeled 52) is shown held in the center of the probe sleeve (here labeled 68). Near the end of the probe, the probe can be seen making a sharp right angle bend as it exits the main body of the instrument. Just proximal to this right angle bend, the probe (52) can be seen firmly locked in place by a probe flange (56) that is located within a flange channel (58). The flange channel (58) is fully enclosed within the interior walls (60) of the instrument and prevents any translational motion by the probe (52).

Hence, it is immediately apparent that this structure is not analogous to the "prime mover (130)" of the instant apparatus, because Freitas' probe does not move.

Instead, it is the probe sleeve (28, in Fig. 3; 68, in Figs 1 and 2; and 112, in Fig. 4) of Freitas that moves and actuates the surgical tool (20, in Fig. 1). This is made clear in the specification at Col 4, lines 48-53 where it is stated:

> The interior walls 60 and 62 of the probe frame body 50 also form a channel 70 which slidably receives probe sleeve 68 to allow movement of probe sleeve 68 along its longitudinal axis and is dimensioned to prevent substantial movement along the latitudinal axis of probe 52.

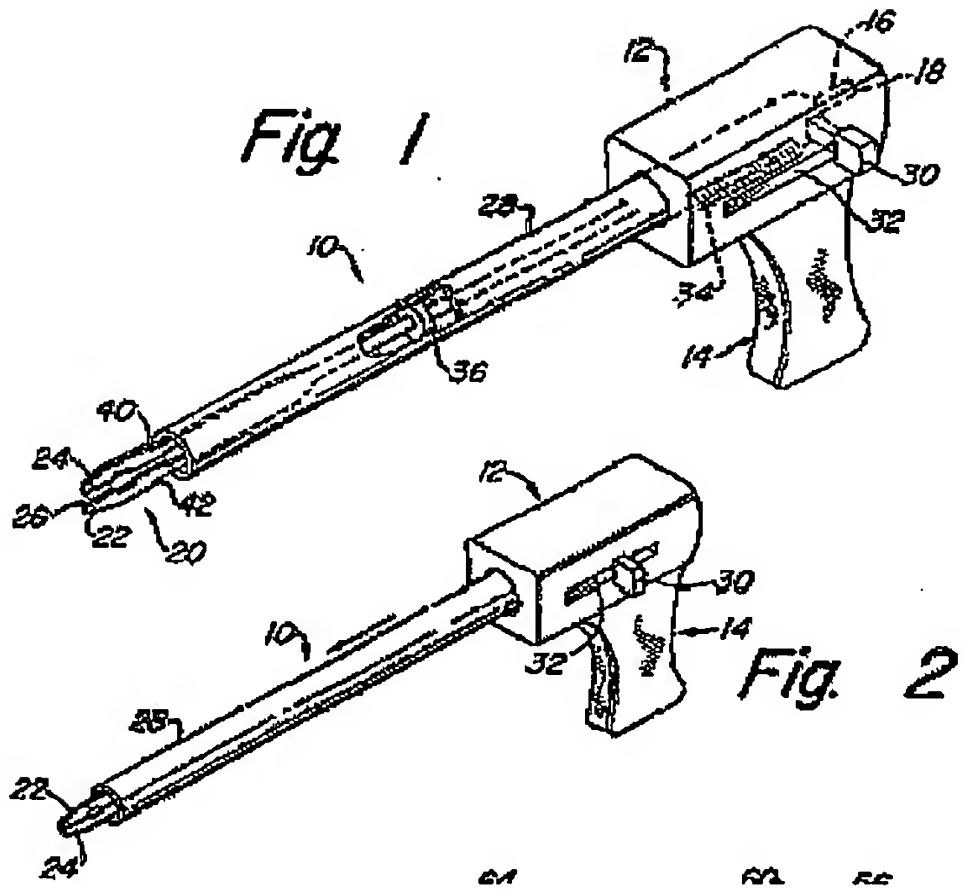
This is best seen in Fig. 4:



(Fig. 4 of Freitas)

This illustration is a transverse section of an embodiment of the entire apparatus of Freitas. The probe sleeve (here labeled 112) is seen surrounding the fixed probe (here labeled 104). The apparatus is actuated by squeezing the trigger handle (140), which causes the notched groove (144) to rotate forward, pushing the sleeve flange (132) forward. A probe sleeve stop (134) is provided to prevent the probe sleeve (112) from being pushed too far out of the body of the apparatus.

The actuation of the tool is best seen in Figs. 1 and 2



(Fig. 1. – Freitas with the tool jaws in an open position; Fig. 2 Freitas with the tool jaws in a closed position)

The leading edge of the probe sleeve (28) advances on the surgical tool (20) squeezing the camming surfaces (40, 42) of the tool (20), causing the jaws (22, 24) of the tool (20) to shut.

This type of structure is easily differentiated from the instant mechanical structure as seen in Fig. 4 of the present invention.:

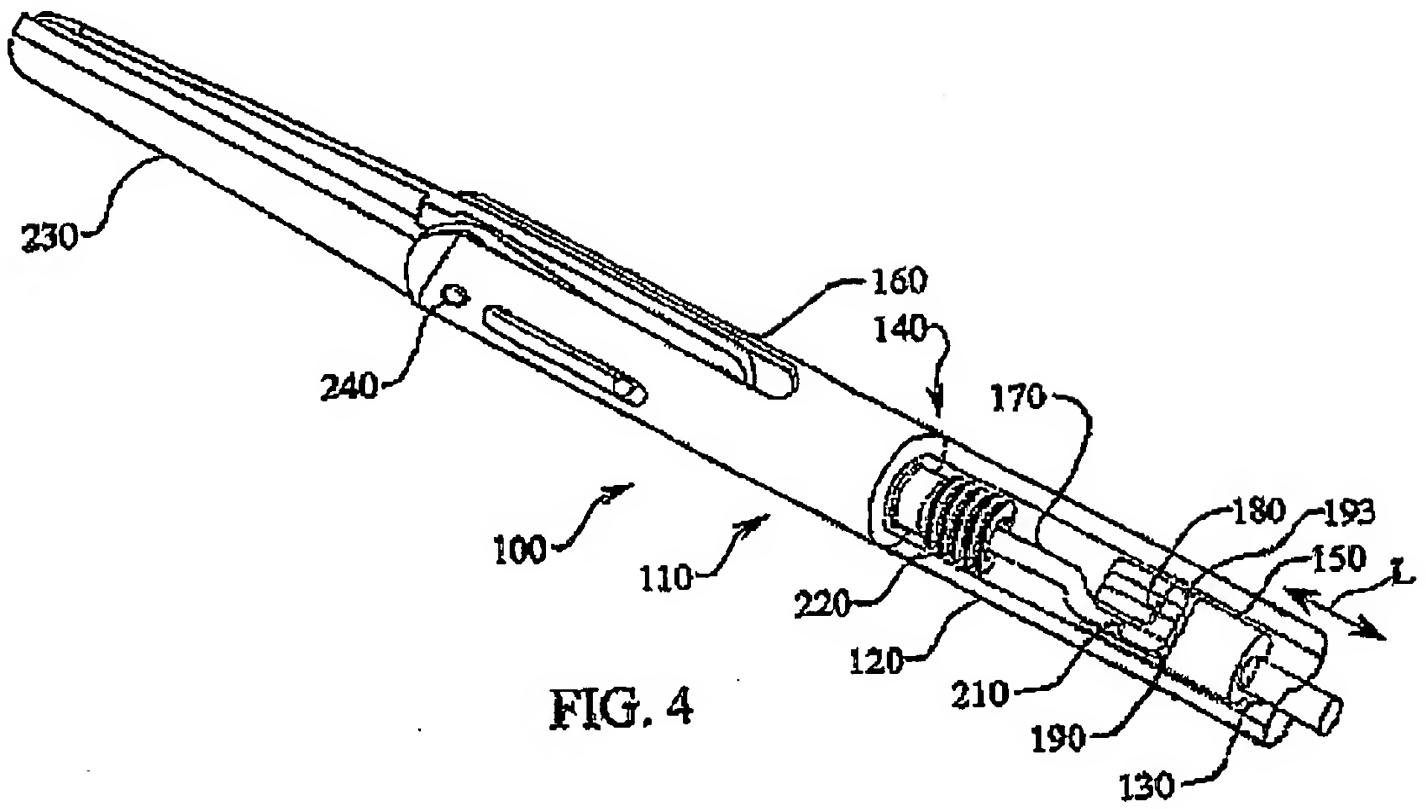


FIG. 4

(Fig. 4 of the instant invention. The prime mover (130) moves translationally within the shaft (120)

The prime mover (130), as the name indicates, moves with translational motion in the direction of the arrows "L" seen above. The prime mover is completely enclosed within the manipulation shaft (120) which does not move translationally at all. This is essentially a complete reversal of the principles of Freitas.

These differences are not a design choice and have significant functional ramifications. As argued previously (Applicant's Appeal Brief at pps 29-31, a moving outer shaft, in use, will continuously move back and forth through a surgical incision, contaminating the incision, and the camming action results in constant danger of pinching and disrupting delicate living tissue.

2. The Examiner Mistakes The Term "Rotably Engage" For The Ability To Transfer Rotable Force In The Freitas Device; And The Freitas Probe, Because Of The Nature Of Its Engagement With The Surgical Tool, Cannot Transfer Rotational Force.

The Examiner, in his Answer, continues to incorrectly equate rotable engagement with the ability to impart rotational force. They are not the same, and while Freitas may posses the former, it cannot effect the latter.

Details of the connection between Freitas' probe (labeled 104 in Fig. 4 below) and the surgical tool (labeled 114 in Fig. 8 below) are seen in Figs. 4, 7 and 8. The probe(104) end, seen in Fig. 7 below, has an instrument flange (106) and cylindrical body (108) that represents an enlarged "button" end that nestles within a substantially "T" shaped aperture, called the coupling channel (122, in Fig. 8), in the proximal end of the tool, best seen in Figs. 7 and 8:

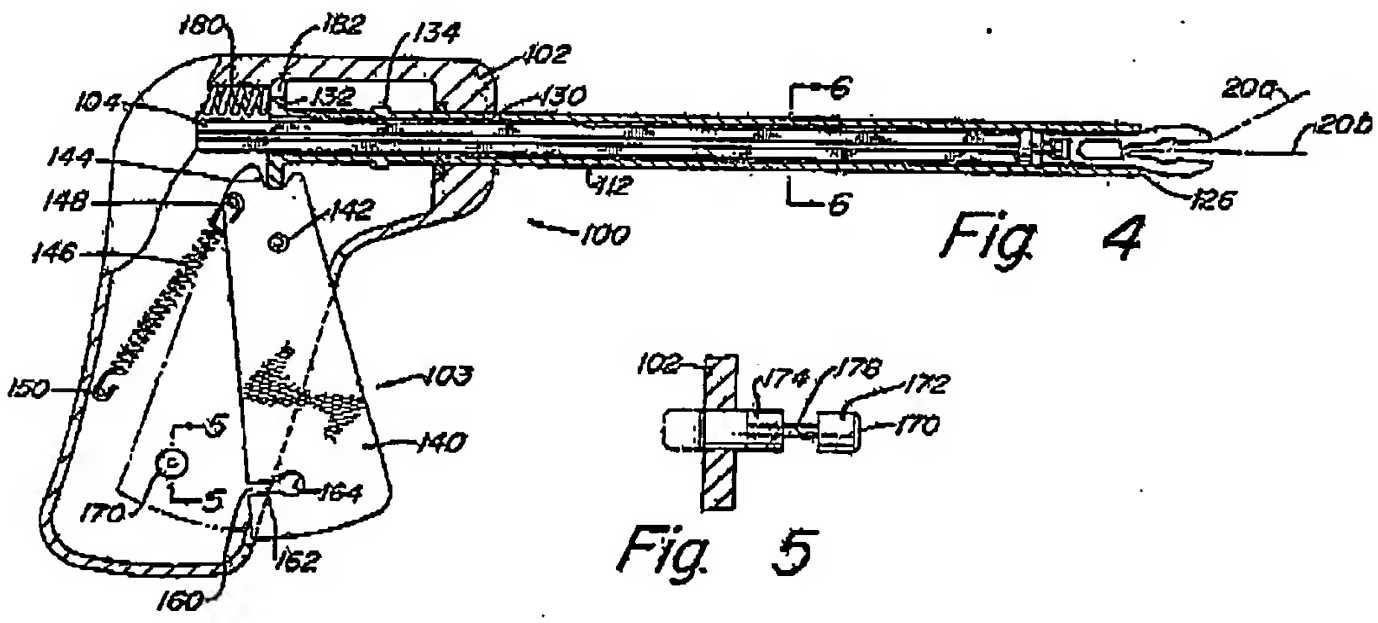
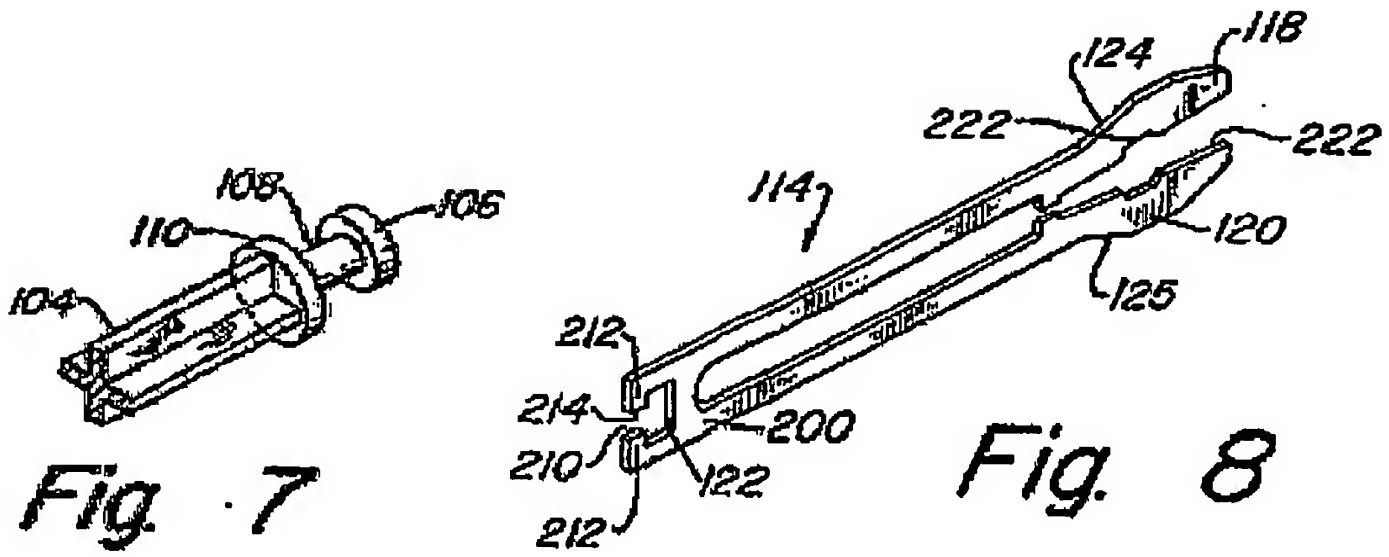


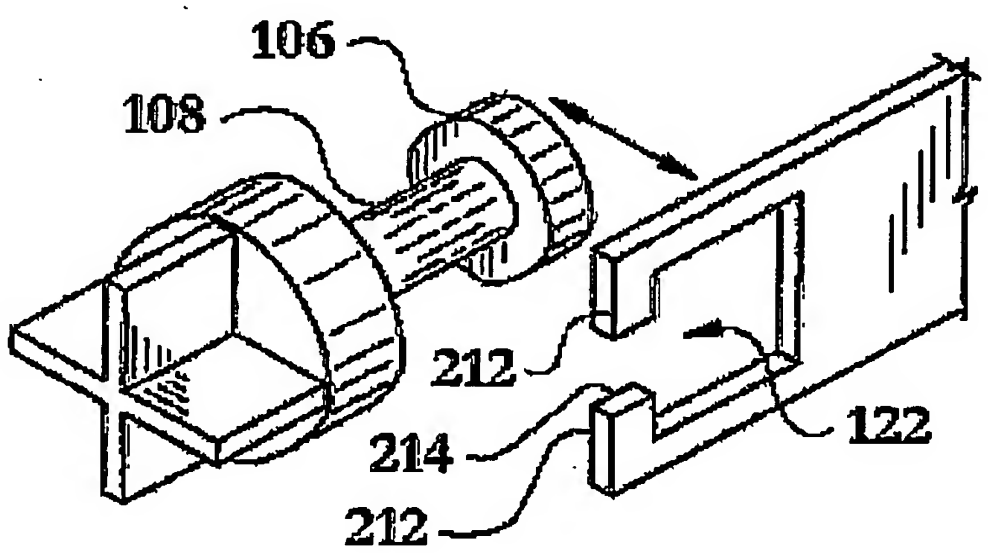
Fig. 4

Fig. 5

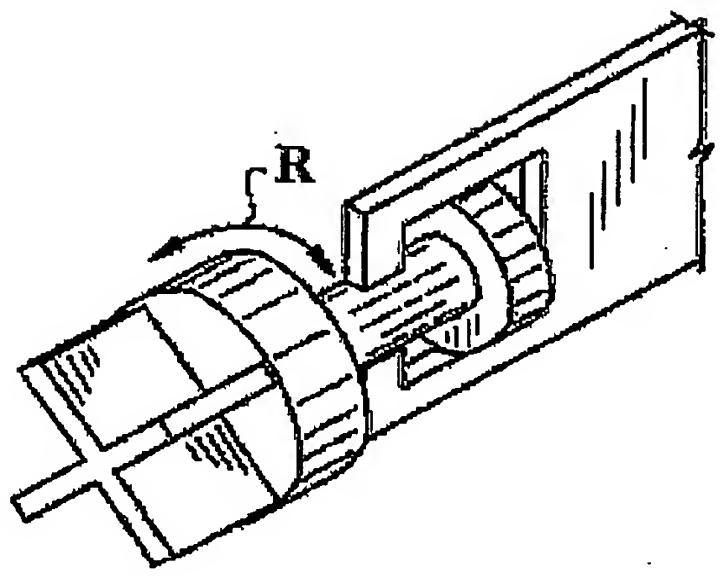


(Figs. 4, 7, and 8 of Freitas, showing how the button like cylindrical body 108 fits within the T-shaped coupling channel 122. Any rotational force on the cylindrical body 108 will simply cause the body to spin within the confines of the coupling channel 122, with no rotational force being transmitted to the tool 114.)

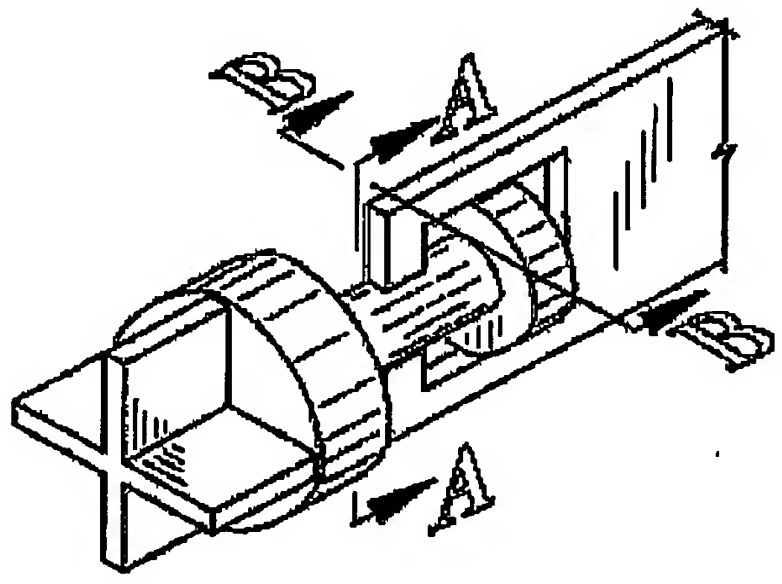
The small size and poor quality of the reproduction of Figs. 7 and 8 of Freitas make it helpful to consider the following rendition of those figures, with sections taken to represent an end on view of the structures of Figs. 7 and 8:



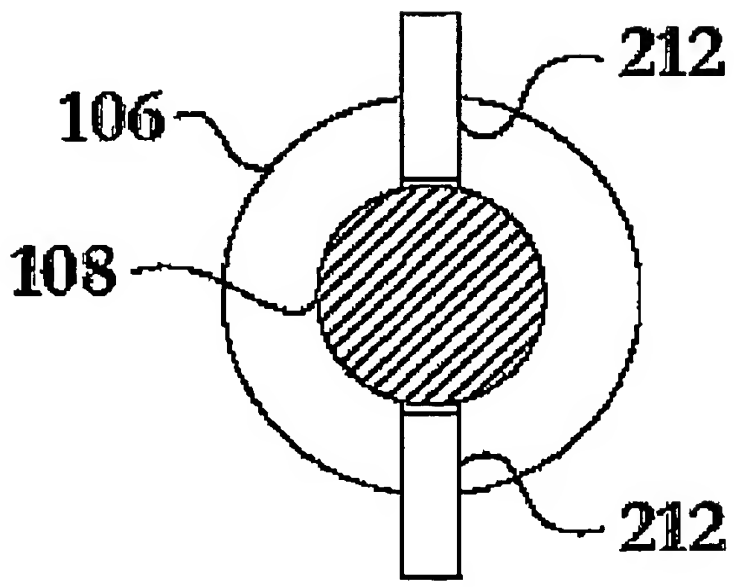
Rendition 1 (immediately above); Combining Figs. 7 and 8 of Freitas



Rendition 2 (immediately above); based on Figs. 7 and 8 of Freitas, showing the free rotation that would result from placing the instrument flange (106) and cylindrical body (108) within the coupling channel (122) of Freitas.

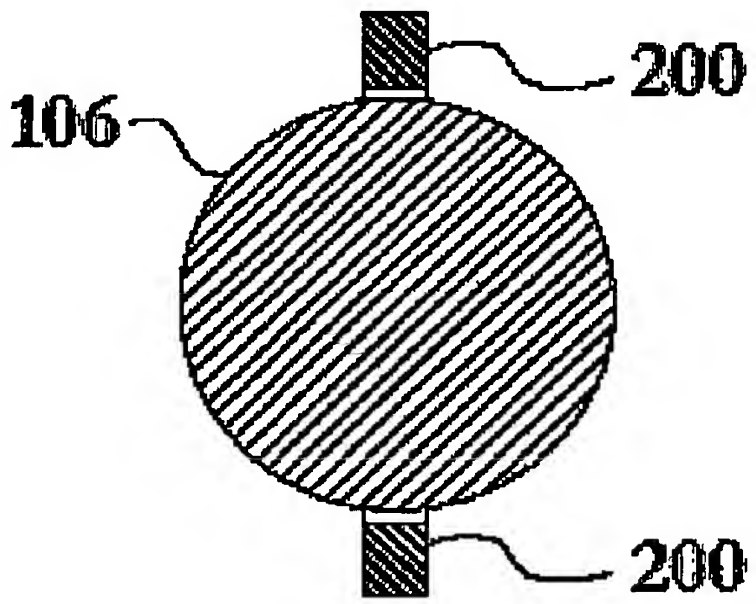


Rendition 2(a) (immediately above) of Rendition 2; showing sections (below) detailing the fit of the probe end within the tool.



SECTION A-A

Section A-A (immediately above) shows that the projections (212) bearing against the wall of the cylindrical body (108) would create no impediment to the free spin of the probe (104) end within the tool (114) Even were the bearing surfaces of element 212 slightly curved, as disclosed at Col. 6, line 67 to Col 7, line 2 of Freitas, this would not alter the basic spinning nature of the probe-tool interface.



SECTION B-B

Section B-B (immediately above) shows that the instrument flange (106) bearing against the walls of the T-shaped coupling channel (210) would create no impediment to the free spin of the probe (104) within the tool (114).

It may readily be seen that while the button may be said to be "rotably engaged" within the T-shaped aperture, the turning of the button will not produce any degree of rotational force on the coupling channel (122) – it will simply cause the button to spin within the aperture. By way of analogy, one could say that an automobile wheel is rotably engaged to an automobile, yet the turning of the wheel does not impart rotational force to the automobile because it is free to spin.

More tellingly, the Examiner states in his Answer (Examiners Answer at pps. 3, 4 and 5) that "Freitas is fully capable of imparting rotational force from the prime mover to the tool (p.3) because it is "capable of transferring ("rotatably engage", col 7:13) rotational force from the prime mover (316) to the tool (240)(col 7:10-15; col 7:42-45; col. 7:51-55; …." The exact language of the cited passages makes no such claim of any ability to impart rotational force, as the actual cited passages are seen here:

> At the proximal end, scissors instrument body 240 has a T-shaped channel 244 form [sic] by projections 246. The dimensions of T-shaped channel 244 are such as to enable scissors instrument body 240 to receive and rotatably engage instrument flange 106 and cylindrical body 108.
>
> '185 at col. 7, lines 10-14

> Also, the embodiment of FIG. 1 can be provided with an instrument head which is rotatable by providing an instrument flange and cylindrical body of such as those illustrated in FIG. 7.
>
> '185 at col. 7, lines 42-45

> FIG. 10 shows another embodiment of the present invention. Again, a probe 316 is provided having one end adapted for receiving an instrument in rotatable attachment, comprising an instrument flange 318 adjacent to a cylindrical body 320 of reduced diameter.
>
> '185 at col. 7, lines 51-55

The Examiner also states in the Answer (Answer at p. 4 and 5) that evidence for his position may be found in the "limitations for 'rotatably coupled' jaws in patent claims

1, 3, and 5." Yet the language of these cited claims is clear evidence that Freitas probe does not impart rotational motion to the tool.

The relevant language, repeated in all three claims, is, "at least the jaws being freely rotatable relative to the handle to permit the handle to be rotated relative to the jaws with the jaws in a selected position in the bodily cavity. ('185 at claims 1, 3, and 5)

If the handle is rotated relative to the jaws with the jaws in a selected position in the bodily cavity, then there must not be any rotational motion imparted between the two elements, or else the jaws would no longer be in the selected position, but would have turned along with the handle and probe. Hence, the claims describe the jaws as being "freely rotatable," indicating that they do not impart rotational motion.

This is reinforced and fully supported by the specification, which the Examiner's analysis fully reads out of the patent:

> Also, the embodiment of FIG. 1 can be provided with an instrument head which is rotatable by providing an instrument flange and cylindrical body of such as those illustrated in FIG. 7. This permits the instrument head to be oriented prior to insertion of the instrument in the incision gasket and into the patient. In the event a different orientation is desired, the apparatus may be removed from the patient and the instrument head rotated to the desired orientation and reinserted into the patient. [emphasis added]

'185 at col. 7, lines 42-47

If the probe were capable of imparting rotational motion to the tool, there would be no need to follow the cumbersome procedure, recited above, of removing the tool from the body, re-orienting the tool, and then reinserting it in the body. It would be sufficient merely to rotate the probe. Therefore, the very instructions for use by Fretias et al. indicate that the probe imparts no rotational force to the tool.

In contrast, the hook-shaped time at the distal end of the prime mover (130) of the instant invention will inescapably transmit any rotational movement of the prime mover (130) to the tool.

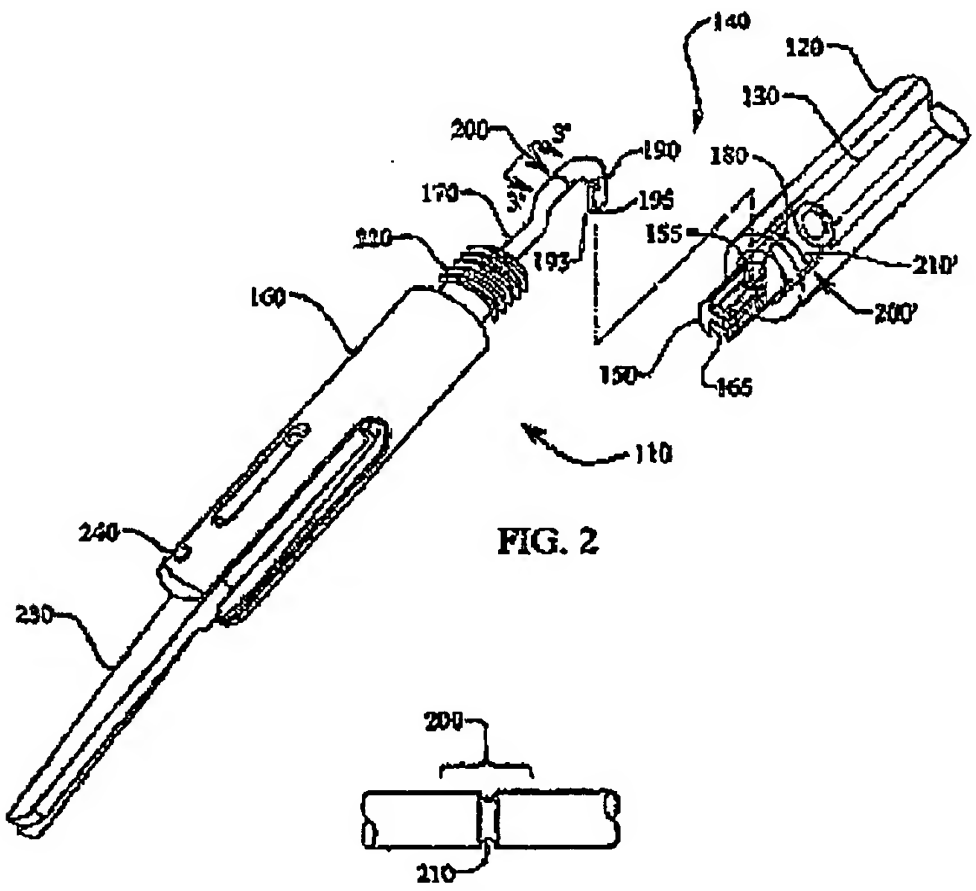


FIG. 2

FIG. 3

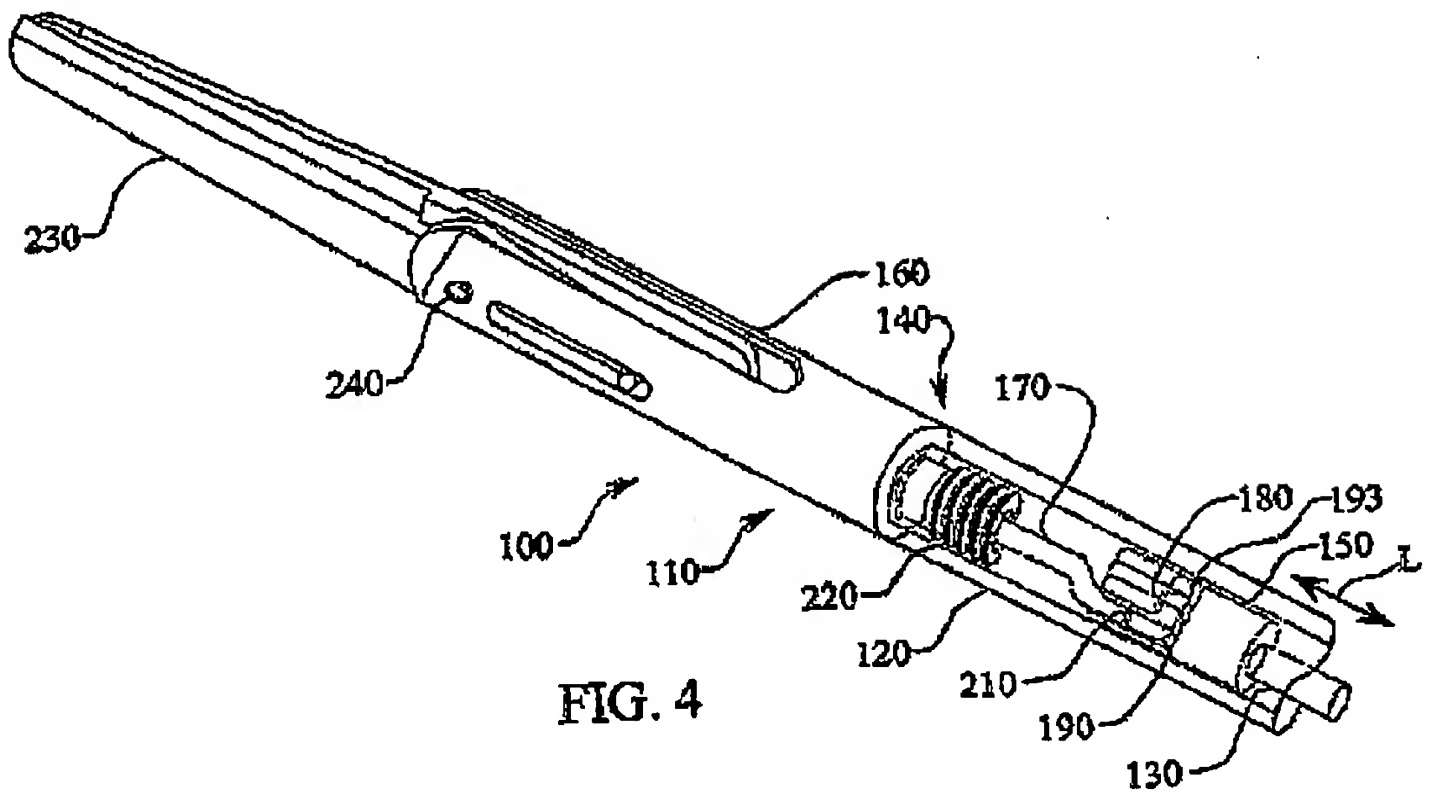


FIG. 4

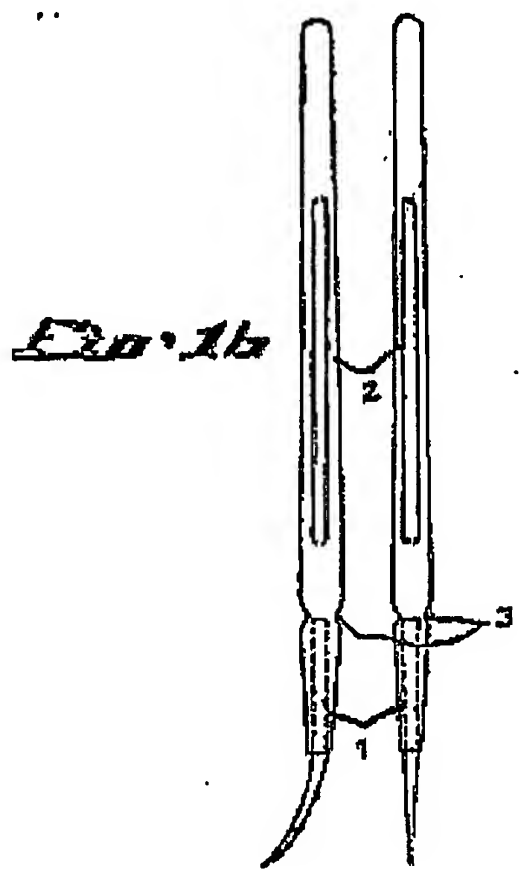
(Figs. 2 and 4 of the instant invention. As contrasted with the inability to impart rotational force seen in Freitas, above, it can readily be seen that the substantially orthogonal orientation of the hook shaped tine 190 relative to the translational axis of the prime mover 130 necessarily results in any rotational force applied to the prime mover 130 being immediately and fully transferred to the tool 160.)

3. Unlike The Instant Invention, Freitas Has No "Frangible Portion."

Within the field of medical engineering, a "frangible portion" of an instrument would be commonly defined as a section that is designed to fail at a lower stress level than the remainder of an instrument, so that over-stressing the instrument results in controlled failure at a predetermined location and/or in a predetermined manner.

The Office Action states in respect of Freitas that "Frangible is simply defined as 'breakable.' Of course the proximal section of element 200 in Fig. 8 is breakable." (OA at page 4, second paragraph). While perhaps true in some contexts, in the medical instrument and other design fields, the term frangible is generally accepted as meaning facilitating breakage in a controlled manner in a controlled location, as seen in the Chien

reference (GB 2227412A) provided by the Examiner. The frangible section in Chien is seen in Fig. 1b, and described on page 4 as, "The neck 3 having a reduced cross sectional area is thereby weakened so as to provide a frangible area which is easy to break."



(Fig. 1b of Chien. While all parts of the probe are potentially breakable, and therefore "frangible" as that term is defined by the Examiner; the Chien patent specifically identifies as the "frangible area," an area of reduced thickness to allow the probe to predictably break at that point.)

Additionally, the specification clearly indicates the instant inventor has defined the term with the same definition of "frangible portion" seen in Chien. This same definition of frangible as seen in Chien is provided at length in the instant application:

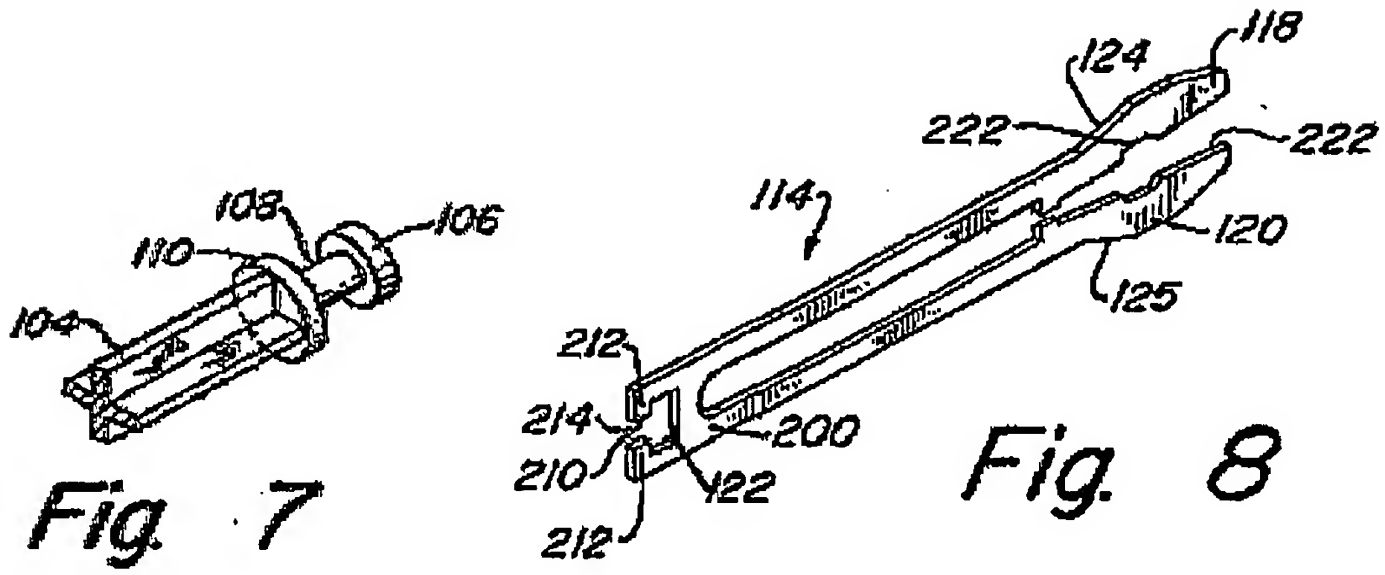
> For purposes of continued illustration, the frangible portion **200** reflected in the various figures, including FIGS. 2 and 3 is shown to be formed as a circumferential region of reduced diameter, or a generally toroidal, parabolic, or counter-sink shaped shear-type notch **210** that is formed about a portion of the anchor **170**. A similar frangible portion (not shown)

> can be implemented wherein the frangible portion **200** may be replaced or augmented with a region that is formed by a material of construction of the anchor **170** in the region of the frangible portion **200** to be weaker than the surrounding material of the anchor **170**. This can be accomplished with either a non-circumferential notch, a diametrical or lateral notch formed in the anchor **170**, or functional equivalents thereof. In yet additional examples, the frangible portion **200** may also be formed wherein the material of the anchor **170** material is selected to have a material strength that is reduced in the region of the frangible portion **200** relative to the other portions of the anchor **170**. Another variation may include forming a circumferential score about the anchor **170** in the region of the frangible portion **200**. An additional method includes forming at least one non-circumferential shear notch, which may be similar in cross-section to the notch **210**, within the frangible portion **200** by removing material from the anchor **170** by machining, or by molding the anchor **170** to have the illustrated shear notch **210** or some similar feature.
>
> Instant Application (U. S. Patent Application Publication 2003/0114839 at paragraph 0049)

The Examiner instead urges an absurd definition of "frangible," namely, that, "Frangible is simply defined as 'breakable'," and thereby, by extension, any device having a part that breaks would therefore have a "frangible portion." Since any invention that is not a uniform mass of a single material is bound to have some part weaker than the others, by the Examiner's definition, all inventions of more than one part, that might somehow be forcibly torn apart, thereby have "frangible portions." This would not only vitiate any special meaning in the term "frangible portion," but it would completely contradict the careful definition provided in the specification of the instant invention, given above.

Furthermore, the statement made in the Examiner's Answer, at page 6, that "The Office contends that section 122 because its width is not as great as section 200 is "breakable" or "frangible" in the same sense as is a wishbone. To this end, Freitas, discloses a frangible section" is demonstrably not so.

The structures in question are best seen in Fig. 8, along with the corresponding probe end of Fig. 7, of Freitas:



(Fig. 7 - Probe End of Freitas; Fig. 8 - Tool of Freitas)

If the tool (114) of Fig. 8 were made of hardened tool steel, as would be likely in a cutting instrument, it is very possible that the instrument flange (106) or cylindrical body (108) of the probe end (Fig. 7) would fail at a lower stress than any part of the tool. In such a circumstance, the so-called "frangible" section (122) would not fail and would not be at all "frangible," but there would be completely unplanned breakage of the probe end – a complete defeat of the present concept of a frangible portion imparting controlled breakage and rotational motion of the tool.

Lastly, the fact that any broken frangible portions of the instant invention would be retained within the apparatus is not "irrelevant" as claimed by the Examiner (Answer at page. 6). These limitations (e.g., dependent claim language of "wherein the frangible portion is sealed from an exterior environment by the coupler and the manipulation shaft") were specifically added by amendment to the instant application to distinguish in part certain embodiments of the design of the instant invention from that of Freitas, in

which any broken portions of the tool occurring during use will likely immediately fall off into the body cavity.

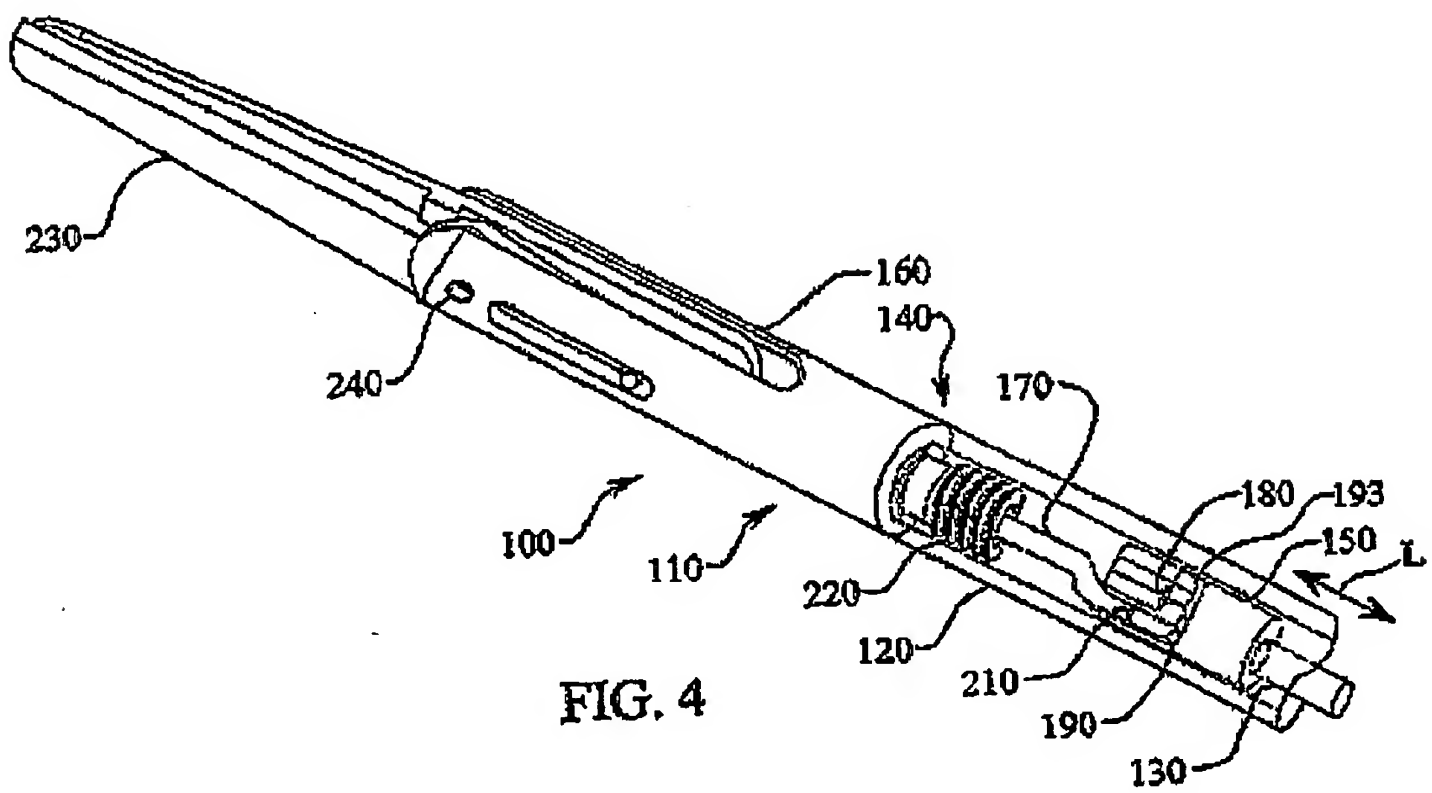


FIG. 4

(Fig. 4 of the instant invention. Compared to the open to the environment arrangement found at the distal end of the Freitas device, these illustrations show how the frangible portions (that portion of the hook distal to the frangible area 210 above) of the instant invention are contained within the device, sealed from the environment and thus necessarily from the patient. In case of breakage at the frangible area 210, any small parts will be contained within the device for easy removal.)

IV. WITHDRAWAL OF THE CHIEN REFERENCE

Applicant acknowledges the withdrawal of the Chien reference as a basis for rejection (Answer at p. 6). Accordingly, Applicant will not make further argument relative to the now-withdrawn §103 rejection based upon Chien.

V. CONCLUSION AND RELIEF REQUESTED

There are three principal reasons why the instant invention is patentable over Freitas. First, Freitas uses a moving outer sheath that pinches the jaws of a non-articulated tool; contrasted with the internal prime mover of the instant invention, fully contained and enclosed within a non-moving outer shaft, which operates an articulated tool by translational motion. Second, the probe of Freitas is not capable of imparting rotational motion to its tool; contrasted with the instant invention in which any rotational motion of the prime mover will be fully imparted to the tool. Third, Freitas does not have a "frangible portion" as that term is both generally defined in the art and specifically defined in the instant application; contrasted to the instant invention, in which a "frangible portion" is provided to facilitate controlled breakage.

Accordingly, Applicant respectfully asks this Board to order the withdrawal of the Examiner's rejections and to allow the application to proceed to issuance.

Date: July 14, 2005

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